



February 28, 2020

VIA E-FILING

The Honorable Maryellen Noreika
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

Re: *Vifor Fresenius Medical Care Renal Pharma Ltd., et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 18-390-MN

Dear Judge Noreika:

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. (“Plaintiffs”) submit this Letter in support of their Motion to Strike the Reply Expert Report of Robert Linhardt, Ph.D., or in the alternative, to preclude Dr. Linhardt from testifying in Defendants’ case-in-chief, such that he could only testify in reply to Dr. Harris’ testimony at trial—if any—on issues of inherency.

The Scheduling Order in this case provides for three rounds of expert reports, with the party bearing the burden of proof on an issue submitting Opening and Reply Reports. D.I. 28 at 6. On November 1st, Defendants Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. (collectively, “Defendants”) served a single opening expert report on issues relating to invalidity from Dr. Walter Chambliss. Dr. Chambliss, who has expertise in pharmaceutical formulation, opined, *inter alia*, that the additional limitations of claims 29, 30 and 31 of the ’251 patent are inherently disclosed by a prior art reference, the ’442 patent, based on the alleged chemical properties of the iron oxy-hydroxide disclosed in the prior art ’442 patent. In response, Plaintiffs submitted a Rebuttal Report from Dr. Wesley Harris, an iron chemist, who explained, *inter alia*, that Dr. Chambliss’ opinions regarding inherency were based on a flawed understanding of iron chemistry. In the third round of expert reports, Defendants served a Reply Report from an entirely new expert, Dr. Linhardt, an organic chemist, who offered new opinions on inherency.

Recognizing the untimeliness of introducing a new expert with entirely new opinions in the third round of expert reports, Defendants try to couch Dr. Linhardt’s Reply Report as being responsive to Dr. Harris’ Rebuttal Report, but in fact Dr. Linhardt is offering entirely new opinions regarding how a skilled person would interpret the disclosure of the prior art references and the inherent properties of material disclosed in the prior art. *See e.g.*, Exhibit 1, Linhardt Reply Report at ¶¶ 48-50, 57-58, 83-87, 94-96, 102, 112-116, 135-138, 147-148. These opinions are designed to replace Dr. Chambliss’ flawed opinions, not to respond to Dr. Harris. Indeed, it was Dr. Linhardt, not Dr. Chambliss, who offered opinions in Defendants’ reply reports that Dr. Harris “misread” Dr. Chambliss’ Opening Report. Instead of addressing Dr. Harris’ alleged “misread[ing]” of his Opening Report, Dr. Chambliss’ Reply Report simply states that

[REDACTED]

Finally, Defendants' intention to use Dr. Linhardt to offer affirmative testimony, and not merely respond to Dr. Harris, was confirmed during the parties' meet and confer on this issue. During that call, Plaintiffs asked Defendants to confirm that they would only call Dr. Linhardt in their rebuttal case and after Dr. Harris had testified on validity issues. Defendants refused to provide this confirmation. The fact Defendants would not provide this assurance further highlights that Dr. Linhardt is not being used solely to respond to Dr. Harris, as would be expected in a reply expert report.

Fed. R. Civ. P. 37(c) precludes a party from relying on late-disclosed evidence "unless the failure was substantially justified or is harmless." In the Third Circuit, the *Pennypack* factors govern whether late-disclosed subject matter should be excluded: "(1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded." *Integra LifeSciences Corp. v. Hyperbranch Med. Tech., Inc.*, 15-cv-819-LPS-CJB, 2018 WL 3814614, at *1 (D. Del. Mar. 23, 2018) (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977)). However, "[c]ourts applying the *Pennypack* factors in the case of sophisticated, complex litigation involving parties represented by competent counsel have been less indulgent in their application and more willing to exclude evidence without a strict showing that each of the *Pennypack* factors has been satisfied." *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, 05-cv-132-JJF, 2007 WL 521894, at *4 (D. Del. February 15, 2007).

The *Pennypack* factors support exclusion of Dr. Linhardt's testimony. It is highly prejudicial to Plaintiffs to be forced to respond to new expert opinions offered in the last round of expert reports. Plaintiffs' experts were deprived of the opportunity to submit an expert report responding to these new opinions despite the fact that Defendants bear the burden on invalidity issues. Moreover, Defendants' tactical decision to introduce a new expert during Reply Reports threatens to severely disrupt the presentation at trial, particularly in light of Defendants' refusal to confirm that they will call Dr. Linhardt only in their rebuttal case. Plaintiffs believe that Dr. Chambliss' opinions in his opening expert report on claims 29-31 fail to establish the inherency of any of these claim limitations by clear and convincing evidence. If Dr. Linhardt was properly being offered to respond to Dr. Harris, his testimony would be limited only to the subject matter of Dr. Harris' testimony at trial—if Dr. Harris testifies on inherency at all. But, Defendants apparently are seeking to fill in deficiencies in their opening expert report by introducing expert testimony in their case-in-chief from an expert whose opinions were only disclosed during the third round of expert reports.

Moreover, Defendants could have provided Dr. Linhardt's testimony during the opening round of expert reports. Dr. Linhardt relies primarily on Dr. Chambliss, the prior art, and Vifor's inventor testimony and internal documents in rendering his opinions regarding the inherent properties of prior art compositions. All of those materials were available at the start of expert testimony. Defendants engaged Dr. Linhardt at least as early as October 11, 2019, before the November 1st Opening Expert Reports were due. Exhibit 4, October 11, 2019 Xiaomei Cai Email disclosing Linhardt. It therefore appears that Defendants' decision to forego submitting an Opening Report from Dr. Linhardt was a tactical decision.

Plaintiffs respectfully request that the Court strike the Reply Expert of Dr. Linhardt as untimely, or in the alternative prohibit Dr. Linhardt from testifying in Defendants' case-in-chief.

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: Counsel of Record (via E-Mail)